

Remarks

I. Amendments

Applicant respectfully requests that the typographical error in the publication indicated in the section entitled Amendments to the Specification be corrected. This amendment is submitted to conform the publication to the specification as originally filed.

Claims 27 and 28 are canceled. Claims 15, 18, 19, and 24-26 are amended to delete “hemangioblast”. Applicant simply claims what he has actually made, and that is:

A purified preparation of mammalian cells which

(i) is capable of proliferation in an *in vitro* culture for more than 40 generations, [see page 29, second paragraph]

(ii) does not induce tumor formation in an immunodeficient Rag1-deficient mouse, [see page 33 line 22 to page 34 line 22]

(iii) maintains the potential to differentiate to hematopoietic and endothelial cells throughout the duration of said culture, and [see page 33 line 20 to page 35 line 13]

(iv) wherein the cells are inhibited from differentiation when cultured on a gelatinized, feeder-free layer. [see page 29, second paragraph; and page 37 lines 5-9]

The cells’ lack of immunohistochemical staining for CD34, PECAM-1 (or CD31), Flk-1, Tie-2, Sca-1, Thy-1 and P-selectin markers (claim 16) is demonstrated at page 31 line 20 to page 32 line 5, and page 37 lines 19-26 and the relevant figures.

Claim 23 is amended to clarify the characteristics of the claimed cell line, as above.

By this amendment, claims 15-26 remain in the instant application.

It is believed no new matter is added. Entry of the amendments is respectfully requested.

II. Traversal of Restriction Requirement

Applicant provisionally elects the claims of Group II (claims 19 to 22), drawn to methods of preparing a mammalian hemangioblast cell line, for prosecution in the subject application, with traverse.

Applicant submits that the pending claims have unity of invention.

(A) The claims are for a combination of categories permitted in a single application.

Annex B (Unity of Invention) of the Administrative Instructions Under the PCT (Appendix AI of the MPEP) states:

(e) Combinations of Different Categories of Claims. The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) [...], or

(iii) [...],

it being understood that a process is specially adapted for the manufacture of a product if it inherently results in the product and that an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art.

Thus, a process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words "specially adapted" are not intended to imply that the product could not also be manufactured by a different process. [...].

The presently pending claims include an independent claim for a product, an independent claim for a process specially adapted for the manufacture of that product, and an independent claim for a use of that product. The claims are therefore drawn to a combination of categories permitted in a single application.

(B) The claims share "special technical features".

Rule 13.2 of the PCT states that unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features". The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

The Examiner cites Lacaud et al. 2001. Annals of the NY Academy of Sciences, Vol 938 pages 96-108 ("Lacaud"), asserting that hemangioblasts are known in the art so the claims do not share unifying special technical features. Applicant disagrees.

"Hemangioblast" means that the cells can differentiate into both endothelial and hematopoietic cells (see the second paragraph of page 2 of the specification). This is merely one property of the claimed cells. The claims as amended do not even recite the term "hemangioblast". The claimed cells are defined by four properties, namely they:

- (i) are capable of proliferation in an *in vitro* culture for more than 40 generations,
- (ii) do not induce tumor formation in an immunodeficient Rag1-deficient mouse,
- (iii) maintain the potential to differentiate to hematopoietic and endothelial cells throughout the duration of said culture, and
- (iv) are inhibited from differentiation when cultured on a gelatinized, feeder-free layer.

All the pending claims share the special technical features defined by the four properties. Lacaud does not disclose cells having all four properties and therefore cannot break the inventive link among the claim categories.

(C) Burden of search

Applicant further submits that the subject matter of all the pending claims is sufficiently related that a thorough search for the subject matter of a single independent claim would necessarily encompass a search for the subject matter of the remaining claims. Thus, a search and examination of the entire application could be performed without serious burden. MPEP §803 clearly states that "If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." (emphasis added). It is submitted that this policy should apply in the present application in order to avoid unnecessary delay and expense to Applicants in duplicative examination by the Patent Office.

Conclusion

The Examiner is respectfully requested to reconsider and withdraw the Restriction Requirement and to examine all the claims now pending in this application.

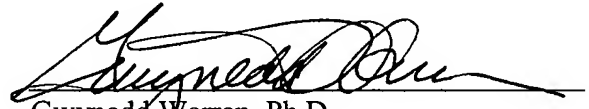
In accordance with this election with traverse, applicants reserve all rights in the non-elected claims, including the right to file one or more divisional applications covering the subject matter thereof.

Respectfully submitted,

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